



Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed new *Rules and Regulations Pertaining to the Rhode Island Traumatic Brain Injury and Spinal Cord Injury Registry (R23-1-TBI)*. These are new regulations proposed in accordance with section 23-1-49 of the Rhode Island General Laws, as amended, for the purpose of establishing a unified procedure for the reporting of traumatic brain injuries and spinal cord injuries to the Department of Health.

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matter, in the **AUDITORIUM** of the Cannon Building (on the lower level), Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island on **TUESDAY, SEPTEMBER 5, 2006 at 10:00 a.m.** at which time and place all persons interested therein will be heard. The seating capacity of the Cannon Building room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.


In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach or duplication or overlap was identified based upon available information. The health, safety, and welfare of the public precludes any economic impact that may be incurred as a result of these regulations.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches, overlap, or significant economic impact, be submitted in writing at the time of the hearing or mailed prior to the hearing date to: David R. Gifford, M.D., M.P.H., Director, Rhode Island Department of Health, #401 Cannon Building, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

Copies of the regulations are available for public inspection in the Cannon Building, Room #404, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Department's website: www.health.ri.gov/hsr/regulations/index.php or the Secretary of State's website: <http://www.sec.state.ri.us/rules/> by calling 401-222-1039, or by e-mailing: LizS@doh.state.ri.us.

The Cannon Building is accessible to the handicapped. Individuals requesting interpreter services for the hearing impaired must notify the Office of Health Services Regulation at 401-222-1600 (Hearing/speech impaired, dial 711) at least 72 hours prior to the hearing.

Signed this 21st day of July 2006



David R. Gifford, M.D., M.P.H., Director of Health

RULES AND REGULATIONS
PERTAINING TO THE RHODE ISLAND
TRAUMATIC BRAIN INJURY AND SPINAL CORD
INJURY REGISTRY
(R23-1-TBI)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

August 2006 (Proposed)

NOTE: Statutory language noted in *italics*.

INTRODUCTION

These Rules and Regulations Pertaining to the Rhode Island Traumatic Brain Injury/Spinal Cord Injury Registry (R23-1-TBI) are promulgated pursuant to the authority conferred in Section 23-1-49 and Chapter 42-35 of the General Laws of Rhode Island, as amended, and are promulgated for the purpose of establishing a unified procedure for the reporting of traumatic brain injuries and spinal cord injuries to the Rhode Island Traumatic Brain Injury Spinal Cord Injury Registry maintained by the Rhode Island Department of Health.

In accordance with the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, in the development of the regulations, consideration was to: (1) alternative approaches to the regulations; and (2) duplication or overlap with other state regulations. Based on the available information, no known alternative approach, duplication or overlap was identified. The health, safety and welfare of the public overrides any economic impact that may be incurred from these regulations.

TABLE OF CONTENTS

	<i>Page</i>
1.0 Definitions	1
2.0 General Requirements	2
3.0 Reportable Injuries	2
4.0 Validation of Data	4
5.0 Confidentiality	4
6.0 Violations/Sanctions	5
7.0 Exception and Severability	5
References	6

Registry of Persons with Head Injuries and/or Spinal Cord Injuries

Section 1.0 *Definitions*

Wherever used in these rules and regulations the following terms shall be construed as follows:

- 1.1 ***"Act"*** means section 23-1-49 of the General Laws of Rhode Island, as amended.
- 1.2 ***"Traumatic brain injury"*** means all injuries as defined by the International Classification of Disease, 9th Revision Clinical Modification, codes: 310.2, 800, 801, 803, 804, 850, 851, 852, 853, 854, 959.01, 905.0, and 907.0.
- 1.3 ***"Spinal cord injury"*** means all injuries as defined by the International Classification of Disease, 9th Revision Clinical Modification, codes: 806, 952, and 907.2.
- 1.4 ***"Department"*** means the Rhode Island Department of Health.
- 1.5 ***"Director"*** means the Director of the Department of Health.
- 1.6 ***"Hospital"*** means a facility licensed in Rhode Island with a governing body, an organized medical staff and a nursing service providing equipment and services primarily for inpatient care to persons who require definitive diagnosis and treatment for injury, illness or other disabilities or pregnancy. A hospital shall provide psychiatric and/or medical and/or surgical care and at least the following services: dietetic, infection control, medical records, laboratory, pharmaceutical and radiology, except that a psychiatric facility need not provide radiology services.
- 1.7 ***"Registrar of the Traumatic Brain Injury/Spinal Cord Injury Registry"*** hereinafter referred to as Registrar, means the person within the Department designated by the Director to be responsible for the operation of the Rhode Island Traumatic Brain Injury/Spinal Cord Injury Registry.
- 1.8 ***"Rhode Island Traumatic Brain Injury/Spinal Cord Injury Registry"*** means the central registry established within the Department by the Director pursuant to the Act as the statewide registry for the collection and recording of information on all cases of traumatic brain injuries and spinal cord injuries for the purpose of describing the occurrence of traumatic brain injury and spinal cord injury among Rhode Islanders; detecting trends of morbidity and mortality, stimulating epidemiological research, diminishing the impact of these injuries; and identifying survivors of these injuries in order to intervene on a timely basis for treatment.

Section 2.0 *General Reporting Requirements*

All newly diagnosed traumatic brain and/or spinal cord injuries and the submission of any specified additional information on reported injuries that the Director deems necessary and appropriate for the recognition, prevention, or control of those injuries shall be reported to the Department in the manner described herein.

- 2.1 All cases of traumatic brain injury and spinal cord injury as listed in section 3.1 diagnosed on and **after January 1, 2007** shall be reportable by hospitals in accordance with the statutory and regulatory provisions herein. Reporting is required for all such injuries occurring in Rhode Island.
- 2.2 The administrative officer, or his/her designee, of each hospital shall be responsible for establishing the reporting procedures at that facility. These procedures shall ensure that every case that is diagnosed either in the facility-operated inpatient or emergency department shall be reported to the Registry. If an injured person is transported to another facility, the health care facility in which the reportable diagnosis is first made shall be responsible for reporting. This reporting requirement also applies in cases where the person dies before discharge from the facility.
- 2.3 Within fourteen (14) days from the date of diagnosis or confirmation of a new case of a reportable traumatic brain injury or spinal cord injury as listed in section 3.1 herein, a hospital shall report in the manner specified by the Department all the information and data requested. The originating hospital shall retain a duplicate copy of submitted information for a two (2) year period from the date of submission.
- 2.4 Nothing under the provisions of the Act and the rules and regulations herein shall be construed to compel any individual to submit to medical or Departmental examination or supervision.

Section 3.0 *Reportable Injuries*

- 3.1 Hospitals shall report those injuries identified by the following selected codes listed in the publication entitled, "International Classifications of Diseases, 9th Revision, Clinical Modification" of reference 1 herein:

Traumatic Brain Injury		Spinal Cord Injury	
310.2	post concussion syndrome/post traumatic encephalopathy	806	fracture, vertebral column with spinal cord injury
800	skull fracture (vault)	952	spinal cord injury
801	skull fracture (base)		
803	other and unqualified skull fractures		
804	multiple fractures of skull and face with other bones		
850	Concussion		
851	cerebral laceration/contusion		
852	SAH, SDH & EDH with SD injury	905.0	skull fracture
853	other and unspecified IC hemorrhage	907.0	intracerebral injury
854	IC injury other and unspecified	907.2	spinal cord injury
959.01	head injury unspecified		

3.2 Each hospital shall submit data in such a manner as to make uniform a system of periodic reporting and shall include no less than the following detailed statistical data and information:

- a) Patient's full name;
- b) Social Security number;
- b) Street address, city or town, state and zip code at the time of diagnosis;
- c) Date of birth;
- d) Sex;
- e) Ethnicity: Hispanic or Latino; Non-Hispanic or Latino;
- f) Race: White; Black or African American; Asian; American Indian or Alaska Native; Native Hawaiian or Pacific Islander; Other;
- g) Date of injury;
- h) Date of admission;
- i) Date of discharge;
- j) Place of incident (ICD-9 Place of Occurrence codes E849);
- k) Traumatic Brain/Spinal Cord Injury related diagnosis (ICD-9 CM codes and description as stated above);
- l) Other diagnosis codes (ICD-9 CM codes and descriptions);
- m) Cause of injury (ICD-9 CM external cause codes E800.0-E999.9);
- n) Initials of person completing the form;
- o) Type of discharge (code specified on form);
- p) Hospital code;
- q) Patient medical record number;
- r) Date form completed.

3.3 Data and information on cases of traumatic brain injury/spinal cord injury shall be reported electronically or by US postal mail unless reporting by another means has been approved in writing by the Director.

- 3.4 Such data and information shall be abstracted from medical charts and other sources of patient information by personnel possessing, at a minimum, a basic working knowledge of medical terminology, human anatomy, and physiology.
- 3.5 Such data and information shall be coded in a manner specified by the Director.
- 3.6 Such data and information shall be submitted with sufficient narrative substantiation to allow a visual assessment of the accuracy of coded data and information.

Rights of Survivors/Parents/Legal Guardians

- 3.7 The Department shall remove identifying information from the registry upon request of the traumatic brain injury/spinal cord injury survivor or legal guardians. The survivor or legal guardian shall also have the right to prohibit being contacted by the Department.
- 3.8 The Department shall provide timely notification to survivors or legal guardians of their rights as stated above.
- 3.9 There shall be written documentation of a survivors or legal guardian's prohibition of the release of individually identifiable information from the traumatic brain injury/spinal cord injury registry. Written documentation shall include, but not be limited to: (1) a survivor or legal guardian's signature maintained on file by the Department, or hospital; or (2) a note regarding the prohibition of release of information entered into the survivor's medical record by the attending health care practitioner.

Section 4.0 *Confidentiality*

- 4.1 *The traumatic brain injury/spinal cord injury registry shall maintain comprehensive records of all reports submitted pursuant to the Act and the rules and regulations herein. These reports shall be confidential in accordance with Chapter 37.3 of Title 5 and subject to the restrictions on release incorporated in that Chapter.*

Ownership and Publication of Data

- 4.2 All individual records and aggregate data including abstract report forms relating to the Rhode Island Traumatic Brain Injury/Spinal Cord Injury Registry are the property of the Department. The use of records and aggregate data by any person shall be subject to the approval of the Director. Furthermore, requests for access to data compiled pursuant to the provisions of these regulations may be granted only by the Director in accordance with applicable federal and state law, rules and regulations regarding confidentiality and public access to data.

Section 5.0 *Violations/Sanctions*

- 5.1 Failure of any health care facility to comply with the provisions of the Acts and the rules and regulations herein shall be subject to sanctions and referred to the appropriate licensing and/or disciplinary body.

Section 6.0 *Exception and Severability*

6.1 Modification of any individual rule and regulation herein may be granted by the Director upon motion of the Rhode Island Traumatic Brain Injury/Spinal Cord Injury Registry or upon request of a contracting agency and/or organization in a specific case, if the Director finds that the modification to the rule is not contrary to the purpose of the Rhode Island Traumatic Brain Injury/Spinal Cord Injury Registry or nor contrary to the public interest.

6.1.1 A request for modification of a rule shall require advance written request to the Director and written approval by the Director.

Severability

6.2 If any provision of the rules and regulations herein or the application thereof to any facility or provider or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

Thursday, July 20, 2006

Tbi-proposed regs-august06.doc

REFERENCES

1. *International Classifications of Diseases*, 9th Revision, Clinical Modification, 1989.